



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Prospective Grant of Start-up Exclusive License: Development of Virus Like Particles for the Treatment of Breast Cancer, Lung Cancer, Melanoma, Pancreatic Cancer, and Hepatocellular Cancer.

**AGENCY:** NATIONAL INSTITUTES OF HEALTH, PUBLIC HEALTH SERVICE, HHS

**ACTION:** Notice

**SUMMARY:** This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7, that the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Patent License to practice the inventions embodied in the following patent applications to Chimeron Bio Corporation, a company incorporated under the laws of Delaware and having an office in Philadelphia, PA.

**Intellectual Property:** U.S. Provisional Patent Application No.: 61/615,687 Entitled “Delivery of Packaged RNA in Mammalian Cells” HHS Ref. No.: E-264-2011/0-US-01 Filed March 26, 2012; International Patent Application No.: PCT/US2013/031876 Entitled “Delivery of Packaged RNA in Mammalian Cells” HHS Ref. No.: E-264-2011/0-PCT-02 Filed March 15, 2013; Australian Patent Application No.: 2013-240248 Entitled “Delivery of Packaged RNA in Mammalian Cells” HHS Ref. No.: E-264-2011/0-AU-03 Filed October 17, 2014; European Patent Application No.: 13712661.1 Entitled “Delivery of Packaged RNA in Mammalian Cells” HHS Ref. No.: E-264-2011/0-EP-04 Filed October 24, 2014; Japanese Patent Application No.: 2015-503322 entitled “Delivery of Packaged RNA in Mammalian Cells” HHS Ref. No.: E-264-2011/0-JP-05 Filed September 25, 2014; U.S. Patent Application No.: 14/388,441 Entitled Delivery of Packaged RNA in Mammalian Cells” HHS Ref. No.: E-264-2011/0-US-06 Filed September 26, 2014; U.S. Provisional Patent Application No.: 61/916,394 Entitled “Cancer Immunotherapy: Delivery HLA-11

using VLP-Replicon” HHS Ref. No.: E-050-2014/0-US-01 Filed December 16, 2013; International Patent Application No.: PCT/US2014/070552 Entitled “Cancer Immunotherapy: Delivery HLA-11 using VLP-Replicon” HHS Ref. No.: E-050-2014/0-PCT-02 Filed December 16, 2014;

The patent rights to these inventions have been assigned to the Government of the United States of America.

The prospective exclusive start-up licensed territory may be worldwide and the field of use may be limited to: “Use of virus like particles comprising MHCII and CD80 for the treatment of breast cancer, lung cancer, melanoma, pancreatic cancer, and hepatocellular cancer.”

**DATES:** Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

**ADDRESSEES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Lauren Nguyen-Antczak, Ph.D., J.D., Sr. Licensing and Patenting Manager, Technology Transfer Center, National Cancer Institute, 8490 Progress Drive, Riverside 5, Suite 400, Frederick, MD 21701; Telephone: (301) 624-8752; E-mail: [lauren.nguyen-antczak@nih.gov](mailto:lauren.nguyen-antczak@nih.gov).

**SUPPLEMENTARY INFORMATION:** The invention is directed to virus-like particles (“VLPs”) that serve to induce transgene expression of at least one recombinant protein of interest in specific, targeted cells. This technology can be used to treat a variety of diseases, depending on the cell type to be targeted. Preferably, invention VLPs may be used to treat tumor bearing cancers, including breast cancer, lung cancer, melanoma, pancreatic cancer, and hepatocellular cancer.

The prospective Start-Up Exclusive Patent License, which will be royalty bearing, is being considered under the small business initiative launched on 1 October 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective Start-Up Exclusive Patent License may be granted unless the NIH receives written evidence and argument, within fifteen (15) days

from the date of this published notice, that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive start-up license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Date: May 12, 2016

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Technology Transfer Center

National Cancer Institute

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